DSIC Teleconference, April 16th, 2004

Data Sharing and Intellectual Capital Working Group Teleconference

April 16, 2004	
Attendees:	Cecchi Consulting: Don Cecchi (patient advocate) Fox Chase : Pat Harsche-Weeks Fred Hutchinson: Robert Robbins Jackson Lab: Carol Bult Oregon Health & Science University: Motomi Mori, Edwin Quick Thomas Jefferson: Jack London University of Iowa: Tom Cassavant University of Michigan: Kevin Smith University of Minnesota: Don Connelly University of Pittsburgh: Mike Becich Washington University: ?? NCI: Wendy Patterson; Leslie Derr Booz Allen Hamilton: Phan Winter (703-465-5723)
Introduction	Wendy Patterson summarized the materials sent to participants prior to the teleconference and reviewed the DSIC WG charter. Chartered responsibilities include: • addressing issues concerning data sharing and intellectual capital in the caBIG project • providing guidance for developing caBIG DSIC standards. • developing documents such as policy statements and white papers to clarify caBIG recommendations for sharing data • providing expert guidance regarding specific areas of concern relayed by DSIC liaisons from other caBIG workspaces and working groups
Contracts Presentation	Denise Tingle presented an overview of the general contracting process. The Basic Agreement was sent to the Cancer Centers for review on Monday, April 12th. It was sent to the attention of the Cancer Center "Contracting POCs, or to primary caBIG project POCs if

	the Contracting POC has yet to be identified. As a next step, each Cancer Center Contracting POC is being called by Denise to ensure the agreement was received, confirm POC information, and schedule a meeting to discuss the agreement and any questions. After the general agreement discussion, a Statement of Work (SOW) will be provided to each Center as directed and prioritized by NCI. Each Center will then respond with a cost proposal and project schedule, which will be reviewed and approved by NCI. Individual task orders will then be issued under the basic agreement for each SOW, which will provide for funding, establish a payment schedule with a goal of monthly payments and allow for work to commence. Payment will be based on submission of deliverables and acceptance by NCI. Monthly status reports and other deliverables submitted to the General Contractor will allow progress to be monitored and facilitate periodic payments. Don Cecchi requested a copy of the general agreement.
Recap Issues	<u>Summary of Working Group Issues</u>: The group thought that the list of issues extracted from the notes of the Kickoff meeting was comprehensive. Wendy noted that the group will likely be adding and refining the list of issues as meetings proceed. Participants can send comments to Phan, who will update the issues document. Leslie Derr suggested that participants send their update comments to the Online Forum so that others may also provide input. The group discussed how to prioritize the issues. Bob Robbins, who participates in the Architecture Workspace, raised the point that rules concerning data access and data sharing will have an impact on architecture. Not all data in the system will be shareable and thus architectural design will have to incorporate features that allow partial access. Wendy asked members to identify their technology

transfer/intellectual property representatives for consultation purposes and to inform them that they may be invited to participate in DSIC Working Group meetings on an occasional basis. Members should provide contact information to Phan.

Data Rights and Ownership

Pat Harsche-Weeks raised questions concerning ownership issues created by preexisting agreements with drug companies (pharma and biotech). Issues frequently arise when information is patentable. Pat stated the view that much of the information to be generated by caBIG participants will have a commodity-like quality as opposed to information relating to diagnostic kits and therapeutics. She also pointed out that it would be very helpful for her institution if she could respond to drug and diagnostic companies with caBIG/DSIC standards.

The group decided that it would be useful to understand the extent to which there is a problem imposed by proprietary restrictions. DSIC should develop a 1-page survey to identify problem areas in agreements that create third party rights in data and impose restrictions on data sharing by cancer centers. Pat volunteered to initiate this survey process. She will start developing a questionnaire and will consult with Wendy off-line during the week of April 26.

Data Sharing Constraints

Bob Robbins identified a second priority that the Architecture Workspace needs the DSIC Working Group to address immediately. The DSIC Working Group needs to communicate quickly that constraints on data sharing are necessary to protect IP rights. The message that some information cannot be shared widely and completely should go out immediately. Patentable data is of high importance to academic institutions such as Cancer Centers participating in caBIG.

Another point was that drug companies impose restrictions that prohibit all data from being shared, i.e., not just Cancer Center patents. Therefore, caBIG will need a robust framework that permits sharing depending on the needs and requirements of the data collectors. The system needs to distinguish between raw data and analyzed data and between pre- and post-publication data.

Thus, the goal of the DSIC working group is to develop a series of best practices for data sharing. If a drug company's restrictions on data flow are too burdensome, then it becomes less valuable as a collaborator. Perhaps the DSIC Working Group can bring the strength of the caBIG initiative to begin to

	address these issues with drug companies. Development of best practices in data sharing will be accomplished through a tiered sharing arrangement that limits access to information that cannot be shared, i.e., patient information and proprietary data. A question was raised as to the meaning of the term "clinomics," which was used in one of the kickoff reports; most did not know. The participants concluded that perhaps the term should be avoided since the meaning is unclear. <u>Medical Records</u> Wendy inquired as to whether the group perceived that sharing clinical data would conflict with state laws protecting patients' rights in their medical records. The group thought that there were currently no such issues because data will only go into a study, not into a patient's medical records. It was noted that there are different goals for research vs, clinical data, and the fact that clinical data is striving for 100% accuracy while research is striving for 100% consistency). Clinical research studies are more tolerant of a few errors, whereas such errors are not acceptable for patient care. This could become an issue if at some point the research data were to be included in a patient's medical record and also needs to be considered as we integrate data collected from sources with inherent differences in their "goals". <u>Pharm/Biotech Participants</u> The group considered whether the DSIC WG should begin to identify pharm/biotech participants. Don Cecchi recommended that the DSIC working group think about setting up an official advisory group, which could eventually include a broad cross section of people. The group discussed the value of having pharma and biotech representatives involved in the caBIG initiative and agreed that representatives from pharma and biotech should be invited on occasion to advise DSIC Working Group members.
Liaison	Phan will compile a list of DSIC participants that also participate in at least one other Working Group, and from this list, potential liaisons will be identified.
Special Interest Groups:	The group indicated that they are not interested in establishing SIGs to address the two major areas of the work space where distinct issues may arise, data sharing and software

	development. The group is small enough that it can function as one big group
Key Points	• Restrictions on data access and data sharing will affect architecture. • There are a number of ownership issues created by preexisting agreements. • Constraints on data sharing are necessary to protect IP rights. • Relationships with Pharma/Biotech will be beneficial.
Action Items:	

Name Responsible	**Action Item**	**Date Due**	**Notes**
All	IP contact	4/29/2004	
Phan	Schedule regular telecons	4/23/2004	
Phan	Liaison list – cross section	4/30/2004	
Patricia Harsche-Weeks and Wendy Patterson	Develop questionnaire on third party rights and obligations	4/29/2004	Meeting with Wendy week of 4/26/2004
Phan	Send out telecon date/time poll	4/20/2004	Regularly scheduled biweekly meeting Thurs. at 2pm (ET)
Denise	Send agreement to Don Cecchi	4/20/2004	